

Notice of Allowability

Application No.

10/525,748

Examiner

Karen Cheng

Applicant(s)

FUKUSHIMA ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to declaration filed 06/29/07.
2. ☒ The allowed claim(s) is/are 1.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Claim 1 is currently pending in the instant application.

Response to Applicant's Arguments

Applicants' response to the previous Office Action, filed on 06/29/07 has been fully considered and entered into the application.

The declaration under 37 CFR 1.132 filed 06/29/07 is sufficient to overcome the rejection of claim 1 based upon 35 USC 103(a). Applicant has shown that the benzenesulfonate salt of (2S, 4S)-2-cyano-4-fluoro-1-[(2-hydroxy-1,1-dimethyl)ethylamino]acetylpyrrolidine is easier to crystallize than its most structurally similar crystalline salt, the tosylate salt of (2S, 4S)-2-cyano-4-fluoro-1-[(2-hydroxy-1,1-dimethyl)ethylamino]acetylpyrrolidine. Additionally the benzenesulfonate salt of the claimed invention can be re-crystallized from various solvents in the same polymorph form, and shows no indication of hydrate formation. Applicant has also argued that Test Examples 1-3 of the specification show the benzenesulfonate salt of the claimed invention is more resistant to moisture and is more stable when stored under hot and humid conditions (40 °C, 75% RH) than the corresponding hydrochloride salt conventionally used and the structurally similar methanesulfonate salt of the claimed invention. In view of the evidence presented, the rejection of Claim 1 under USC 103(a) has been withdrawn. The provisional obviousness-type double patenting rejection of Claim 1 has been withdrawn.

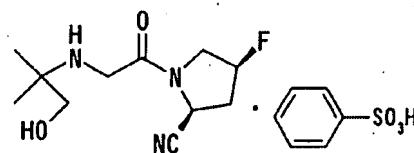
Reasons for Allowance

The following is an examiner's statement of reasons for allowance.

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This invention relates to the benzenesulfonate salt of (2S, 4S)-2-cyano-4-fluoro-

1-[(2-hydroxy-1,1-dimethyl)ethylamino]acetylpyrrolidine



The closest prior art(s) have been made of record (see Non-Final Rejection, mailed 03/30/07, EP 1 333 025 A1 in view of Berge et al., Journal of Pharmaceutical Sciences, Vol. 66, p. 1-19) and disclose the free acid of the claimed compound as well as potential pharmaceutical salts but they fail to teach or suggest the improved crystallization properties from various solvents and better storage properties of the benzenesulfonate salt compared to the structurally similar methanesulfonate salt, or the most commonly used hydrochloride salt.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAMALA A. SAEED, PH.D.
PRIMARY EXAMINER



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31 July 2007

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